

July 27, 2020

Volcano Corporation Brian Park Sr.Regulatory Specialist 3661 Valley Center Dr Suite 200 San Diego, California 92130

Re: K123482

Trade/Device Name: ReFLOW Aspiration Catheter

Regulation Number: 21 CFR 870.5150 Regulation Name: Embolectomy catheter

Regulatory Class: Class II

Product Code: QEZ

## Dear Brian Park:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 29, 2013. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S Digitally signed by Gregory W. O'connell -S
Date: 2020.07.27 07:55:58

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Gregory O'Connell
Assistant Director
Plaque Modification Devices Team
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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Advisory Action	Application No.	Applicant(s)		
	09/419,305	MARUTA ET AL.		
	Examiner	Art Unit		
	Rebecca E. Prouty	1652		
Th MAILING DATE of this communication appe	ears on the cover she t with the c	correspondence address		
THE REPLY FILED 23 October 2003 FAILS TO PLACE Therefore, further action by the applicant is required to a final rejection under 37 CFR 1.113 may only be either: ('condition for allowance; (2) a timely filed Notice of Appe Examination (RCE) in compliance with 37 CFR 1.114.	void abandonment of this application application application and the standard application	cation. A proper reply to a ch places the application in		
PERIOD FOR RE	EPLY [check either a) or b)]			
a) The period for reply expires 3 months from the mailing date of b) The period for reply expires on: (1) the mailing date of this Advevent, however, will the statutory period for reply expire later the ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS 706.07(f).	risory Action, or (2) the date set forth in th an SIX MONTHS from the mailing date o FILED WITHIN TWO MONTHS OF THI	f the final rejection. E FINAL REJECTION. See MPEP		
Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee nave been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).				
1. A Notice of Appeal was filed on Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.				
2. The proposed amendment(s) will not be entered because:				
(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);				
(b) ☐ they raise the issue of new matter (see Note below);				
(c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or				
(d) They present additional claims without canceling a corresponding number of finally rejected claims.				
NOTE:				
3. Applicant's reply has overcome the following reject	• • • • • • • • • • • • • • • • • • • •			
4. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).				
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: <u>See Continuation Sheet</u> .				
6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.				
7. For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.				
The status of the claim(s) is (or will be) as follows:				
Claim(s) allowed: none.				
Claim(s) objected to: none.				
Claim(s) rejected: 1.				
Claim(s) withdrawn from consideration: <u>none</u> .				
8.☐ The drawing correction filed on is a)☐ app	proved or b) disapproved by	the Examiner.		
9. Note the attached Information Disclosure Stateme	ent(s)( PTO-1449) Paper No(s).			
10. Other:		Tuberen Frent		
		Rebecca E. Prouty Primary Examiner Art Unit: 1652		

U.S. Patent and Trademark Office PTOL-303 (Rev. 11-03) Continuation Sheet (PTOL-303) 09/419,305

Continuation of 5. does NOT place the application in condition for allowance because: the amendment to Claim 1 do not overcome the enablement and new matter rejections of the claim. While as applicants argue the specification provides support for variants of SEQ ID NO:1 in which one or more amino acids are replaced, deleted or added, the further limitation of not having the amino acid sequence of SEQ ID NO:3 and/or SEQ ID NO:4 defines a subgenus not contemplated in the specification as filed. As such this recitation introduces new matter. Applicants argue that the enablement rejection should be withdrawn as mutagenesis techniques as well as assay techniques are routine in the art and could be used to define substitutions which could be made. While such techniques might be sufficient for one of ordinary skill in the art to make and use variants with only a few substitutions by making several variants and testing for those which retain the claimed properties, such experimentation would clearly be undue for those polypeptides with large numbers of substitutions as the likelihood of a variant sequence retaining the claimed properties of the native polypeptide decreases substantially with each additional mutation while the number of possible variants which could be made increases exponentially. As such the claimed variants (i.e., those which retain the claimed physicochemical properties of the native polypeptide) with larger numbers of mutations are a very minute fraction of the possible variants which could be made and the experimentation required to make and test all the possibilities would clearly be undue.

## **Indications for Use Statement**

510(k) Number K123482		Page 1 of 1		
<b>Device Name</b>	ReFLOW® Aspiration	n Catheter		
Indications for Use	The ReFLOW Aspiration Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary, carotid and peripheral vasculature.			
Prescription UseX (Per 21 CFR 801.109)		OR	Over the Counter Use	
PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED				
Concurrence of CDRH, Office of Device Evaluation (ODE)				

Matthew G. Hillebrenner

## **510(K) SUMMARY**

**SPONSOR:** Volcano Corporation

3661 Valley Centre Drive Suite 200

San Diego, CA 92130

**CONTACT/SUBMITTER:** Brian Park

Senior Regulatory Affairs Specialist

Volcano Corporation

3661 Valley Centre Dr. Suite 200

San Diego, CA 92130 Tel: (858) 720-4176

**DATE OF SUBMISSION:** April 5, 2013

**DEVICE:** Volcano ReFLOW<sup>®</sup> Aspiration Catheter

Trade Name: ReFLOW Aspiration Catheter

Common Name: Catheter, Embolectomy Classification: 21 CFR Part 870. 5150

Class II Device

**PREDICATE DEVICE:** Lumen Medical Xtract Aspiration Catheter

**DEVICE DESCRIPTION:** The ReFLOW Aspiration Catheter is an embolectomy

catheter comprised of a catheter shaft and hub. It is 150cm

long and is available in 6F and 7F diameters.

**INDICATIONS FOR USE:** The ReFLOW Aspiration Catheter is indicated for the

removal of fresh, soft emboli and thrombi from vessels in

the coronary, carotid and peripheral vasculature.

COMPARISON OF The proposed device is substantially equivalent to

**CHARACTERISTICS:** the predicate device. Both devices are aspiration catheters

consisting of a catheter shaft and hub. The proposed ReFLOW Aspiration Catheter is offered in two sizes, identical to the predicate device. The outer and inner shaft

identical to the predicate device. The outer and inner shaft diameters are identical for both the predicate and proposed

devices.

**PERFORMANCE DATA:** Non-clinical device testing was conducted to confirm the

performance of the device. Bench testing was conducted against known standards or product specifications and

evaluated the following:

- Dimensional Verification
- Visual Inspection
- Particulate Evaluation
- Tube to Stopcock Tensile Strength
- Tube to Luer Tensile Strength
- RX Notch Tensile Strength
- Hub to Shaft Tensile Strength
- Loading Tool Tensile Strength
- Liquid Leak Pressure Test
- Wall Integrity Test
- Guidewire Loading Test
- Torque Strength
- Coating Adhesion Test
- Kink Resistance
- Liquid Aspiration Leak Test
- Aspiration Flow Rate
- Thromboemboli Aspiration Simulated Use Testing

Biocompatibility testing was conducted on the device and the following tests were successfully completed:

- Cytotoxicity
- Intracutaneous
- Systemic Toxicity
- Maximum Sensitization
- Material Mediated Pyrogen
- ASTM Hemolysis
- In Vitro Hemolysis
- C3a Complement Activation
- SC5-b Complement Activation
- Partial Thromboplastin Time
- In vivo Thromboresistence
- Limulus Amebocyte Lysate

Completion of these tests concluded the ReFLOW catheter is substantially equivalent to the predicate device.